DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 20, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-02

Jeremy M. Clayson, Manager
Cedar Arch-North
710 East 600 North
Firth, Idaho 83236

Dear Mr. Clayson:

WARNING LETTER

On August 2 and 3, 2004, U.S. Food and Drug Administration investigators conducted an inspection at your farm located in Firth, Idaho. This inspection confirmed that you offered an animal for sale for food that was adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused an animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about May 18, 2004, you offered for sale a cow with the back tag number [redacted] identified on USDA-FSIS Lab Form #433589. The cow was sold for slaughter as human food to [redacted], who in turn then sold the beef carcass to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of oxytetracycline at 84.99 parts per million (ppm) in the kidney, 42.76 ppm in the liver, and 12.85 ppm in the muscle.

A tolerance of 12 ppm has been established for residues of oxytetracycline in kidney tissue, 6 ppm in liver tissue, and 2 ppm in muscle tissue (21 CFR 556.500). In addition, the USDA analysis identified the presence of sulfadimethoxine at 1.0 ppm in the liver and 1.47 ppm in muscle tissue. The tolerance for sulfadimethoxine in edible tissue is 0.1 ppm (21 CFR 556.640). The presence of these drugs in excess of the established tolerances in the edible tissues of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Other conditions include the following: no records for the treatment of the above-referenced cow with either oxytetracycline or sulfadimethoxine; use of drugs other than by their labeled directions without a valid Veterinarian-Client-Patient-Relationship; and failing to maintain adequate animal treatment record. Food from animals held under such conditions is adulterated under Section 402(a)(4) of the Act.

You also caused the adulteration of [redacted] brand of oxytetracycline amphoteric injectable when you used it to treat a dairy cow contrary to the product's approved labeling. You administered oxytetracycline in excess of the labeled dose without a prescription for such use. The extralabel use of an approved drug is allowed if the use complies with Section 512(a)(4) of the Act and 21 CFR Part 530. Because your extralabel use of Bio-Mycin was not in compliance with 21 CFR Part 530, the drug is unsafe within the meaning of Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

This is not an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

We note that this is not the first residue associated with your farm. On or about August 1998, October 1998, and February 1997, you offered for sale cattle as human food. USDA analysis of tissue samples collected from these animals identified the presence of sulfadimethoxine in excess of the established tolerances for edible tissue.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within 15 working days of the steps you have taken to bring your farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure: 21 CFR 556.500 and 556.640
21 CFR 530

cc: Lael Alberg, DVM
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501